PECEIVED
JUL 0 5 2000

#18/M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue patent application of:

LIN

Serial No. 09/084,441

Filed: May 27, 1998

Title: OPHTHALMIC SURGERY METHOD USING

NON-CONTACT SCANNING LASER

Group Art Unit: 3739

Examiner: Michael Peffley

Client Reference: LIN

Attorney Docket: 62-575

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

AMENDMENT

Dear Sir:

Responsive to the Office Action dated March 31, 2000, the Applicant respectfully requests that the following amendments and remarks be entered in the subject application.

CLAIMS

Please cancel claims 25, 27, 31, 33, 34, 42, 50-52, 56, 61, 62, 73, 74, 77, 79, 84, 86, 92, 96 and 99-104, without prejudice.

Kindly amend the claims as follows:

24. (Twice Amended) A method for performing ophthalmic surgery comprising:

providing a laser <u>having a fundamental ultraviolet wavelength within a range</u> of 193-220 nm exiting from said laser such that said laser emits [outputting] a pulsed laser beam having a repetition rate of [at least 20] 1 Hz to 1000 Hz, and an energy level of no greater than 10 mJ per pulse from [an output coupler of] said laser;

applying said pulsed laser beam onto corneal tissue; and scanning said pulsed laser beam in a substantially overlapping pattern on said corneal tissue.

39. (Twice Amended) A method for performing ophthalmic surgery comprising:

providing a laser <u>having a fundamental ultraviolet wavelength within a range</u> of 193-220 nm exiting from said laser such that said laser emits [outputting] a pulsed laser beam having a repetition rate of [at least 20] 1 Hz to 1000 Hz, and an energy level of [no greater than] 0.5 to 10 mJ per pulse from [an output coupler of] said laser;

scanning said pulsed laser beam in a substantially overlapping pattern on said corneal tissue.

Ŋ

48. (Twice Amended)) A method of performing laser ablation on tissue, said method comprising:

providing a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from said laser such that said laser emits [outputting] a pulsed laser beam having a repetition rate of [at least 20] 1 Hz to 1000Hz, and an energy level of no greater than 10 mJ per pulse from [an output coupler of] said laser;

providing a galvanometer scanner; and

controlling said pulsed output beam with said galvanometer scanner to provide a substantially overlapping pattern of beam pulses on said tissue.

69. (Twice Amended) An apparatus for ablating tissue, comprising:

a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from said laser and adapted to emit a pulsed output beam having [an ultraviolet wavelength and] a repetition rate of [at least 50] 1 Hz to 1000 Hz; and

a scanner constructed and arranged to control said pulsed output beam into a substantially overlapping pattern of beam pulses on said tissue.

76. (Twice Amended) An ophthalmic surgery apparatus for performing corneal refractive surgery by reshaping a portion of a corneal surface, said apparatus comprising:

a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from said laser and adapted to emit a pulsed laser beam having an energy level of less than 10 mJ per pulse from [an output coupler of] said laser; and

a computer-controlled scanning device coupled to said laser to cause overlap of pulses of said pulsed laser beam on said corneal surface to achieve a smooth ablation of corneal tissue.

78. (Twice Amended) A method of performing corneal refractive surgery by reshaping a portion of corneal surface, said method comprising:

having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from said laser;

Clp

substantially overlapping a plurality of ultraviolet laser beam pulses over an area of a corneal surface sufficient to ablate a depth of between 0.05 and 0.5 microns of corneal tissue per ultraviolet laser beam pulse;

said laser beam pulses having an energy level of no greater than 10 mJ per pulse from an output coupler of said laser; and

said laser beam pulses having a pulse repetition rate of [at least 50] 1 to 1000 pulses per second.

82. (Twice Amended) An ophthalmic surgery apparatus, comprising:

a laser <u>having a fundamental ultraviolet wavelength within a range of 193-220</u>
<u>nm exiting from said laser and adapted to emit a pulsed beam of less than about 10 mJ per pulse [at an output coupler of] from said laser; and</u>

a computer-controlled scanning device coupled to said laser such that pulses of said beam are substantially overlapped to achieve a smooth ablation of corneal tissue.

90. (Twice Amended) A method for performing corneal refractive surgery by reshaping a portion of corneal surface, comprising:

selecting a laser having <u>a fundamental ultraviolet wavelength within a range</u> of 193-220 nm exiting from said laser such that said laser emits a pulsed output beam of ultraviolet wavelength and having an energy level less than 10 mJ/pulse from [an output coupler of] said laser;

selecting a scanning mechanism for scanning said laser output beam; coupling said laser beam to said scanning mechanism for scanning said laser beam over a predetermined surface;

focusing said scanning laser beam onto said corneal surface;

controlling said scanning mechanism to deliver the scanning laser beam in an overlapping pattern onto a plurality of positions on said corneal surface to at least one of photoablate and photocoagulate corneal tissue; and

removing from 0.05 to 0.5 microns of corneal tissue per pulse overlapped to remove tissue to a desired depth, whereby a patient's vision is corrected by said reshaping of said portion of said corneal surface of said patient's eye.

91. (Twice Amended) A method for performing ophthalmic surgery, comprising:

providing a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from said laser such that said laser emits a pulsed [pulsing an] ultraviolet laser beam having an output energy level of no greater than 10 mJ/pulse from [an output coupler of] said laser;

applying said pulsing ultraviolet laser beam onto corneal tissue; and scanning said pulsing laser beam in a purposefully substantially overlapping pattern on said corneal tissue.

93. (Once Amended) The method of performing ophthalmic surgery according to claim 91, wherein:

said pulsing ultraviolet laser beam is pulsed at a repetition rate of [at least 50] 1 to 1000 Hz.

REMARKS

Claims 1-24, 26, 28-30, 32, 35-41, 43-49, 53-55, 57-60, 63-72, 75, 76, 78, 80-83, 85, 87-91, 93-95, 97, 98, 105 and 106 remain pending in the application, with claims 25, 27, 31, 33, 34, 42, 50-52, 56, 61, 62, 73, 74, 77, 79, 84, 86, 92, 96 and 99-104 being canceled herein.

Introduction

In the Office Action the Examiner based his rejections of the claims largely on L'Esperance '608 and Ren.

L'Esperance '608 does not disclose, teach or suggest corneal ablation as claimed by the present invention. Rather, L'Esperance '608 relates to the removal of a cataractous <u>lens</u>, and the <u>protection</u> of the cornea from the harmful laser.

A cataract is an opacified lens of an eye. The lens of an eye is <u>separate</u> from the cornea. For instance, the iris is located between the lens and the cornea. The lens (potentially including a cataract) is encapsulated in its own chamber of the eye. The cataracts removed by L'Esperance '608 do NOT remove corneal tissue.

In fact, as will be discussed, L'Esperance '608 specifically taught away from ablation or any damage whatsoever to corneal tissue. In particular, L'Esperance '608 teaches that if laser light is to reach the cornea, that it must do so in a diffuse manner to avoid removal of corneal tissue. (See, e.g., L'Esperance '608, col. 3, line 27)

Moreover, L'Esperance '608 teaches a 'stitching' method whereby laser pulses are placed side-by-side, not substantially overlapped as in the present invention.

Ren, also relied on heavily by the Examiner, does not relate to a <u>scanned</u> laser beam. Rather, Ren teaches the movement of a target with respect to a FIXED laser beam. (Ren, page 130, sec. 2.2, first par.) This is quite distinguishable from the scanned laser beam of the present invention. A scanned laser beam requires particular mechanics and optics not required of a FIXED laser beam. Ren also discloses the use of a laser having an energy level FIVE TIMES as great as that claimed by the present invention.

In responding to the Office Action, the Applicants first discuss the rejections of the patented claims 1-23 articulated by the Examiner on pages 6-8 of the Office Action, then go back to discuss the rejections of the pending reissue claims articulated by the Examiner on pages 3-5 and 8-14 of the Office action.

The Patented Claims 1-23

L'Esperance '608, Bille and Ren

In the Office Action starting on page 6, the patented claims 1-3, 11-18, 22 and 23 were rejected under 35 U.S.C § 103 as allegedly being obvious over L'Esperance '608 in view of U.S. Pat. No. 4,838,679 to Bille ("Bille") and Ren. The Applicant respectfully traverses the rejection.

L'Esperance '608 relates to the removal of <u>cataracted</u> tissue <u>without</u> damaging or <u>removing corneal tissue</u>. L'Esperance '608 is very specific that "[w]hatever laser selected for use of the invention, it will be understood that power levels are selected to . . . be of no harm to . . . the cornea" (L'Esperance '608, col. 3, lines 23-28). Those of ordinary skill in the art would have been directed <u>away</u> from the use of L'Esperance for teaching the removal of corneal tissue by its own disclosure.

Bille teaches a method for examining eyes.

Ren teaches the removal of corneal tissue using a fundamental <u>infrared</u> laser system having a FIXED (i.e., <u>non</u>-scanned) laser beam.

It is respectfully submitted that the use of L'Esperance '608 for the purpose of

arriving at a laser which <u>removes</u> corneal tissue is in direct contradiction to the explicit teachings of L'Esperance '608, which instructs that a laser is to be chosen which does NOT damage the cornea. It is respectfully submitted that the combination of L'Esperance '608 (which teaches to not harm the cornea) with Ren (which teaches the removal of corneal tissue) is nonsensical, and improper as it relates to the patented claims 1-23 of the present invention, and can only be explained using improper hindsight of the present invention.

Bille relates to the <u>examination</u> of eyes. Bille contains no disclosure or teachings relating to corneal reshaping. Those of ordinary skill in the art of refractive surgery would NOT have looked to Bille to arrive at an improved method for performing corneal reshaping, as recited by the patented claims 1-23 of the present invention.

Accordingly, it is respectfully submitted that the combination of L'Esperance '608 with Bille and/or with Ren is improper as it relates to the use of an <u>ultraviolet</u> ablating laser beam to <u>reshape</u> a corneal surface, as recited by patented claims 1-23.

Even if L'Esperance, Bille and Ren were to be considered properly combinable (which they are not), even the combination of all three of these references still fails to teach or suggest the invention of patented claims 1-3, 11-18, 22 and 23.

In particular, patented claims 1-3, 11-18, 22 and 23 recite, *inter alia*, the following features not taught or suggested by the combination of L'Esperance '608, Bille and Ren:

(a) A method of performing corneal refractive surgery by **reshaping** a portion of a corneal surface.

L'Esperance '608 teaches a method of removing <u>cataracted</u> tissue. L'Esperance '608 fails to teach any method for <u>reshaping</u> a corneal surface. In fact, L'Esperance '608 teaches away from the removal of corneal tissue (See, e.g., L'Esperance '608 at col. 3, lines 23-28). As explicitly stated by L'Esperance '608, "[w]hatever the laser

selected for use of the invention, it will be understood that power levels are selected to achieve the indicated decomposition at the focal spot but to be <u>sufficiently diffuse at entry</u> to the cornea . . . to be of no harm to . . . the cornea" (L'Esperance '608, col. 3, lines 23-28).

Billie fails to cure this deficiency. Bille teaches an apparatus and method for examining eyes. Bille fails to teach any reshaping of a corneal surface.

In combination with L'Esperance, Ren would, at best, teach the use of a high power laser (minimum 50 mJ/pulse) used in a non-overlapping manner to remove cataracted tissue. L'Esperance '608 teaches the use of a high power laser used in a way which does NOT ablate corneal tissue, as recited by patented claims 1-23. Ren teaches the use of a high power laser in a FIXED, non-scanned manner to ablate corneal tissue.

Accordingly, for these reasons alone, patented claims 1-23 remain patentable over the prior art of record.

(b) Selection of a scanning mechanism including a galvanometer

L'Esperance '608 teaches use of a one mirror, two-axis gimbal system which moves a mirror in X-axis and Y-axis directions, and linear movement of a lens to produce Z-axis movement of a laser beam (L'Esperance '608, col. 3, lines 43-53). L'Esperance '608 fails to disclose, teach or suggest use of a galvanometer as required by the patented claims 1-23.

Similarly, Ren fails to disclose, teach or suggest a galvanometer.

The Examiner cites Bille for allegedly teaching the use of a galvanometer (Office Action at 6).

Bille teaches an examination system which includes a galvanometer mirror (38 in Fig. 1) for scanning an illuminating laser beam. The illumination of image spots on an examination field are detected by a 2D-matrix array of photodetectors.

L'Esperance '608 teaches the pivoting of a very large mirror 22 to provide x-axis and y-axis deflection (See, e.g., L'Esperance '608, Fig. 1 and col. 3, lines 53-62). The mirror 22 is sufficiently large to provide a laser beam which is not collimated, but rather has as much as a 30 degree angle of convergence (L'Esperance '608, col. 3, line 15 and Fig. 1).

Combining Bille with L'Esperance '608 would, at best, teach the use of an illumination laser beam scanned using a single mirror. Certainly, the extremely large mirror 22 disclosed by L'Esperance '608 could not be rotated by galvanometers in two axes sufficiently quickly to perform corneal reshaping. The high convergence angle requirements taught by L'Esperance '608 (e.g., 30 degrees) require the mirror 22 to be located quite close to the patient's eye. Moreover, the inertia alone from moving such a large mirror 22 in L'Esperance '608 would have caused undesirable instabilities in the laser system. It is respectfully submitted that a person of ordinary skill in the art at the relevant time would not have been motivated to replace the pivoting structure of L'Esperance's mirror 22 with Bille's galvanometer.

Accordingly, for these additional reasons, even the combination of L'Esperance '608, Bille and Ren still fails to teach or suggest all elements of patented claims 1-23.

(c) Delivering the scanning laser beam in a predetermined **overlapping** pattern.

L'Esperance '608 teaches, at best, a non-overlapping 'mosaic' technique using "rounded-square spots" wherein laser pulses were 'squared up' and placed edge-to-edge in a <u>non-overlapping</u> manner to form a mosaic pattern, as those of ordinary skill in the art knew of L'Esperance's technique at the time. (See, e.g., EP 0 151 869, already of record in this case)

Bille teaches an examination technique wherein non-overlapping spots are

illuminated and detected by photodetectors.

Ren teaches <u>non-overlapping</u> refractive surgery techniques.

Neither L'Esperance '608, Bille nor Ren teach use of <u>overlapping</u> spots as claimed.

Accordingly, for these added reasons, even the combination of L'Esperance '608, Bille and Ren still fails to teach or suggest scanning a laser beam to form an **overlapping** pattern, as claimed by patented claims 1-23.

(d) Focusing the scanning laser beam onto a corneal surface.

L'Esperance '608 teaches use of an extremely converging laser beam (e.g., up to 30 degrees), having a <u>diffuse</u> (i.e., **non**-focused) entry to the cornea (L'Esperance '608, col. 3, lines 24-26). L'Esperance '608 fails to teach or suggest specific <u>focusing</u> of a scanning laser beam onto a corneal surface.

In fact, not only does L'Esperance '608 teach <u>diffuse</u> application of a laser beam to a corneal surface, but L'Esperance '608 teaches <u>away from focusing</u> the laser beam onto the <u>corneal surface</u>. For instance, L'Esperance '608 specifically warns and instructs that the laser is selected to be "sufficiently diffuse at entry to the cornea . . . to be of no harm to . . . the cornea" (L'Esperance '608, col. 3, lines 23-28)

A proper theoretical combination of Bille and Ren with L'Esperance '608 must at a minimum follow the specific teachings of L'Esperance '608, e.g., to scan the laser beam 'diffusely'. To do otherwise would undermine the 'motivation' of the base reference L'Esperance '608 using hindsight of the present invention, which would be improper.

Accordingly, even the combination of L'Esperance, Bille and Ren still fails to teach or suggest a laser beam <u>focused</u> on a <u>cornea</u>, as claimed by patented claims 1-23.

L'Esperance '608 in view of Billie, Ren and Parel

Patented claims 5-10 and 19-21 were rejected under 35 U.S.C § 103 as allegedly being obvious over <u>four separate references</u>. In particular, the Examiner cites (1) L'Esperance '608 in view of (2) Bille, (3) Ren and further in view of (4) U.S. Pat. No. 5,152,759 to Parel et al. ("Parel") to allegedly make obvious the combination of the elements recited by claims 5-10 and 19-21. The Applicant respectfully traverses the rejection.

It is respectfully submitted that the need to combine as many as <u>four</u> references to identify all elements of the rejected claims is an indication of the **non**-obviousness of patented claims 5-10 and 19-21, not of obviousness as alleged.

Patented claims 5-10 and 19-21 are dependent from patented claim 1, and are patentable for all the same reasons that patented claim 1 is patentable.

The Examiner agrees that even with the combination of L'Esperance '608, Bille and Ren, there is still no disclosure relating to "all the specific types of lasers which may be used to achieve these frequencies." (Office Action at 7). To cure this deficiency, the Examiner cites Parel, indicating that Parel teaches "numerous types of lasers for providing infrared wavelengths" (Office Action at 7).

Parel teaches the use of various lasers useful for "marking a cornea of a patient's or donor's eye in transplanting surgery or keratoplasty, and in incising or excising the corneal tissue in keratotomy, and for tissue welding and for thermokeratoplasty." (Parel, Abstract) Nevertheless, Parel still fails to cure any of the deficiencies (a) to (d) noted above with respect to the alleged combination of L'Esperance '608, Bille and Ren.

Accordingly, it is respectfully submitted that patented claims 1-23, which the Examiner allowed during the original prosecution of the case, remain patentable over the prior art of record.

The Reissue Claims

Section 112, first paragraph rejection

In the Office Action starting back on page 3, claims 24-38, 42, 50, 51, 59, 61, 62, 77 and 86 were rejected under 35 U.S.C. § 112, 1st paragraph, for reciting "at least 20 Hz".

Claims 25, 27, 31, 33, 34, 42, 50, 51, 61, 62, 77 and 86 are cancelled herein, making the rejection of these claims now moot. Claims 24, 39 and 48 are amended herein to recite the exemplary range of 1 Hz to 1000 Hz disclosed and fully enabled, *inter alia*, at col. 8, lines 61-64 in the specification.

All claims are now in full compliance with 35 U.S.C § 112. It is therefore respectfully requested that the rejection be withdrawn.

L'Esperance 608

In the Office Action, claims 24, 25, 27, 34, 37, 39, 42, 43, 46, 69, 71, 75-77, 82, 84, 86, 91 and 93 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pat. No. 4,538,608 to L'Esperance, Jr. ("L'Esperance '608"). Claims 25, 27, 34, 42, 77, 84 and 86 are cancelled herein, mooting the rejection with respect to these claims. Otherwise, the Applicant respectfully traverses the rejection.

Claims 24, 37, 39, 43, 46, 91 and 93 recite the provision of a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of no greater than 10 mJ per pulse. Claims 69, 71 and 75 recite a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser. Claims 76 and 82 recite a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of less than 10 mJ per pulse.

The original specification teaches the use of a basic laser, e.g., at col. 8, lines

7-24 and again at lines 61-64 wherein a <u>low power</u> excimer laser is disclosed having a wavelength of 193 nm with a repetition rate between 1-1,000 Hz, an energy per pulse of 0.5 – 10mJ and pulse duration of 1-50 ns. The low power nature of the laser system is characterized in the claims by their recitation of an energy level of a <u>fundamental</u> wavelength <u>exiting</u> from the laser of <u>no more than 10 mJ/pulse</u>.

The methods and apparatus using a <u>low power</u> ultraviolet laser as disclosed herein provide a system which is much smaller than earlier excimer laser systems and power supplies (e.g., the size of a breadbox vs. the size of a refrigerator). (See, e.g., original patent, col. 5, lines 5-10).

The relevant prior art is void of such a small, <u>low power</u> ultraviolet laser as claimed. For instance, prior art laser systems teach the use of large, <u>high power</u> laser systems, e.g., L'Esperance '608. Many prior art references utilize diaphragms and masks to guide a high powered beam. L'Esperance notoriously used a non-overlapping 'mosaic' technique using "rounded-square spots" wherein laser pulses were 'squared up' and placed edge-to-edge in a <u>non-overlapping</u> manner to form a mosaic pattern.

The cited L'Esperance '608 teaches a method and apparatus for removing cataracted-lens tissue (NOT corneal tissue) at an extremely low energy level on the cataract of between **0.007 mJ/pulse** and **0.392 mJ/pulse** (based on L'Esperance's disclosed fluence of 1 to 5 J/cm2 and spot diameter of 30 to 100 microns).

L'Esperance explains that this energy level as applied to the cornea specifically avoids ablation of corneal tissue. (See L'Esperance '608, Abstract). L'Esperance '608 specifically instructs that a power level on the cornea is to be selected which is "of no harm to either the cornea or the retina". (L'Esperance '608, col. 3, lines 23-28). L'Esperance emphasizes that "whatever the laser selected for use of the invention, it will be understood that power levels are selected to . . . be of no harm to . . . the cornea (L'Esperance '608, col. 3, lines 23-28). L'Esperance '608 teaches the removal of cataracted tissue, not reshaping of corneal tissue.

L'Esperance '608 in general, and particularly at col. 3, lines 23-28, is in contradiction to the present invention which claims a laser for <u>removing</u> corneal tissue to reshape a cornea.

While L'Esperance '608 appears to discloses a <u>u</u>J/pulse energy level applied to cataracted tissue on a lens, it does so using a conventional excimer laser used at the time in the relevant art. L'Esperance '608 does not specifically indicate the size of the laser used, or the energy level of the <u>fundamental</u> output of the excimer laser described in the '608 patent at col. 3, lines 7-22.

The Examiner cites col. 3, line 2 of L'Esperance '608 as allegedly disclosing use of a laser having an energy level of 1 to 30 mJ/pulse. However, a more careful reading shows that this disclosed energy level relates to an <u>infrared</u> laser (L'Esperance, col. 2, line 69), not to a fundamentally ultraviolet laser as claimed. In contrast, claims 24, 37, 39, 43, 46, 91 and 93 clearly recite an <u>ultraviolet laser in the specific range of 193 to 220 nm</u>. L'Esperance '608 fails to disclose an ultraviolet laser having the requisite low power levels sufficient to ablate <u>corneal</u> tissue as claimed herein.

In another patent application (EP 0 151 869) filed by Francis A. L'Esperance, Jr. within months of L'Esperance '608, he discloses the specific model and fundamental energy level of an excimer laser which he was using at the time. In particular, on page 7 of EP 0 151 869 (already of record in this case), Francis L'Esperance explains that the Model EMG 103 from Lambda Physik GmbH, Gottinghen, Germany was used. As disclosed therein, L'Esperance's laser had a fundamental output energy of 200 mJ/pulse-20 times as great as the fundamental energy level claimed by claims 24, 37, 39, 43, 46, 69, 71, 75, 76, 86, 91 and 93.

No low power laser was disclosed by L'Esperance '608-only energy levels applied to cataracted tissue. Thus, not only does L'Esperance '608 fail to teach details regarding the specific excimer laser used in his ultraviolet embodiment, but other art contemporaneously authored by the same inventor Francis L'Esperance would have

directed those of ordinary skill in the art to use a conventional high power laser such as the **200** mJ/pulse laser he was using at the time (See, e.g., EP 0 151 869).

For these reasons alone, claims 24, 37, 39, 43, 46, 69, 71, 75, 76, 82, 91 and 93 are patentable over the prior art of record.

Moreover, claims 24, 37, 39, 43, 46, 91 and 93 additionally recite scanning a pulsed laser beam in a <u>substantially **overlapping**</u> pattern on corneal tissue. According to the present invention, substantial overlap (e.g., 50% to 80%) is found to achieve smoother surface ablation (e.g., col. 12, lines 40-47).

L'Esperance '608 does not disclose overlapping ablating pulses whatsoever. Rather, as was known in the art, Francis A. L'Esperance notoriously taught stitching together ablation pulses to form a mosaic pattern. This is evident from the reference in L'Esperance '608 to a 'raster-like scan' (L'Esperance '608, col. 4, line 1) and to his often repeated references to "rounded-square spots" in other contemporaneous patents (See, e.g., L'Esperance EP 0 151 869).

Claims 39-41 and 43-47 are amended herein to recite a laser having an energy level of **0.5 to 10 mJ per pulse**.

L'Esperance '608 discloses application of a laser pulse having an energy in a <u>micro</u> Joule range as opposed to <u>milli</u> Joules as claimed by claims 39-41 and 43-47. The energy level range exiting at a fundamental wavelength recited by claims 39-41 and 43-47 is completely and by orders of magnitude outside the levels taught by L'Esperance for an ultraviolet laser (e.g., 0.007 mJ/pulse to 0.392 mJ/pulse).

For these and other reasons, claims 24, 37, 39, 43, 46, 91 and 93 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Ren

Claims 24, 27, 28, 31, 33, 36, 38-40, 42, 45, 47, 90-92, 94 and 106 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by an article by Ren et al., which the inventor co-authored, entitled, "Corneal Refractive Surgery Using an Ultraviolet (213 nm) Solid State Laser" ("Ren"). Claims 27, 31, 33, 42 and 92 have been cancelled herein, making the rejection of these claims now moot. With respect to the remaining rejected claims, the Applicant respectfully traverses the rejection.

Claims 24, 28, 36, 38-40, 45, 47, 91 and 94 recite the provision of a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of no greater than 10 mJ per pulse. Claims 90 and 106 recite a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of less than 10 mJ per pulse.

The Examiner cites page 129 of Ren for allegedly teaching an ultraviolet laser which operates at 213 nm. (Office Action at 5)

Ren teaches use of a frequency multiplied Nd:YAG laser to generate fifth (213 nm) and fourth (266 nm) harmonic frequencies to ablate. (Ren, page 129). Ren's laser was a flash-lamp-pumped, Q-switched, Nd:YAG laser (Quantel model 580) having an output energy at a fundamental **infrared** wavelength of 1064 nm of **50** mJ/pulse. (Ren, page 130, para. 2.1). Ren's Fig. 2 clearly illustrates the <u>high</u> power, <u>infrared</u> nature of the <u>fundamental</u> output of Ren's laser system. Ren utilizes frequency multiplication techniques to produce a laser beam at the lower wavelength of 213 nm. Ren's <u>fundamental</u> wavelength is <u>not ultraviolet</u> as claimed by claims 24, 28, 36, 38-40, 45, 47, 91 and 94. (Ren, page 130, para. 2.1)

Not only is Ren's <u>fundamental</u> output wavelength not <u>ultraviolet</u> as claimed, but the energy of the fundamental output wavelength of Ren's <u>infrared</u> laser is <u>50</u> <u>mJ/pulse</u>—<u>FIVE TIMES</u> as great as that claimed by claims 24, 28, 36, 38-40, 45, 47, 91 and 94. (Ren, page 130, para. 2.1)

Moreover, claims 39-41 and 43-47 are amended herein to recite a laser having an energy level of **0.5 to 10 mJ per pulse**.

Ren discloses application of a laser pulse having an energy of at least **50** mJ/pulse--FIVE TIMES the upper range of claims 39-41 and 43-47.

Claims 24, 28, 36, 38-40, 45, 47, 90, 91, 94 and 106 further recite **scanning** the pulsed laser beam.

Ren teaches the use of a FIXED beam which is NOT scanned. Rather, the target is scanned. See, e.g., page 130, section 2.2, first paragraph, where Ren explains that the "laser beam was scanned across the specimens by <u>moving the specimen</u> on a <u>manually driven micrometer</u> to create a linear excision." It is respectfully submitted that the use of a manually driven micrometer to hold the patient would not be practical when reshaping a patient's eye.

Accordingly, for at least all of the above reasons, claims 24, 28, 36, 38-40, 45, 47, 90, 91, 94 and 106 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claim 99

The rejection of claim 99 is mooted by its cancellation herein.

L'Esperance '608 in view of Sumiya

Skipping over pages 6 and 7 of the Office Action relating to the rejection of the patented claims 1-23 which has already been discussed, on page 8 claims 26, 30, 32, 35, 37, 38, 41, 44, 47, 70, 72 and 83 were rejected as allegedly being obvious over L'Esperance '608 in view of U.S. Pat. No. 5,507,799 to Sumiya ("Sumiya"). The Applicant respectfully traverses the rejection.

Claims 26, 30, 32, 35, 37, 38, 41, 44 and 47 recite the provision of a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from

the laser at an energy level of **no greater than 10 mJ per pulse**. Claims 70 and 72 recite a laser having a **fundamental ultraviolet wavelength** within a range of **193-220 nm** exiting from the laser. Claim 83 recites a laser having a **fundamental ultraviolet** wavelength within a range of **193-220 nm** exiting from the laser at an energy level of **less** than **10 mJ per pulse**.

As discussed, L'Esperance teaches use of a near-infrared laser, or an ultraviolet laser of presumably high power (e.g., 200 mJ/pulse), but does so in a way which does not remove corneal tissue. In any event, L'Esperance '608 fails to teach or suggest the provision of a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of no greater than 10 mJ per pulse, as claimed by claims 23, 26, 30, 32, 35, 37, 38, 41, 44 and 47, or a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser as claimed by claims 70 and 72.

The Examiner cites Sumiya for allegedly teaching a scanner to deliver laser energy to tissue wherein the pulses are overlapped. (Office Action at 8)

L'Esperance '608 teaches a method of <u>not</u> removing corneal tissue, while Sumiya teaches a technique for uniform <u>removal</u> of corneal tissue. It is respectfully submitted that Sumiya is not properly combinable with L'Esperance because one of ordinary skill in the art would not have looked to it to improve upon uniformity of corneal tissue ablation given that L'Esperance specifically prohibited the use of any laser which would remove corneal tissue. (See, e.g., L'Esperance '608, col. 3, lines 23-28)

Nevertheless, even if properly combinable (which they are not), the combination of L'Esperance '608 with Sumiya still fails to teach use of a laser having a fundamental <u>ultraviolet</u> wavelength energy level of 10 mJ/pulse, as claimed by claims 26, 30, 32, 35, 37, 38, 41, 44 and 47, 70, 72 and 83.

For these and other reasons, claims 26, 30, 32, 35, 37, 38, 41, 44 and 47, 70, 72 and 83 are patentable over the prior art of record. It is therefore respectfully requested

that the rejection be withdrawn.

L'Esperance '608 combined variously with Ren, Bille and Sumiya

In six (6) subsequent paragraphed rejections in the Office Action, claims 28, 29, 30, 31, 33, 36, 40, 45, 48-52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64-68, 73, 74, 78-81, 85, 87, 88, 89 and 93 were rejected under 35 U.S.C § 103 using L'Esperance '608 as a primary reference.

In particular, claim 30 was rejected as allegedly being obvious over L'Esperance '608, Sumiya and Ren; Claims 28, 29, 31, 33, 36, 40, 45, 73, 74, 78-80, 85 and 89 were rejected as allegedly being obvious over L'Esperance '608 in view of Ren; claim 81 was rejected as allegedly being obvious over L'Esperance '608 and Ren in further view of Bille; claims 48-52, 55, 56, 60, 61 and 87 were rejected as allegedly being obvious over L'Esperance '608 in view of Bille; claims 53, 54, 57-59, 62 and 64-68 were rejected as allegedly being obvious over L'Esperance '608 and Bille in further view of Ren; claims 63 and 88 were rejected as allegedly being obvious over L'Esperance '608 and Bille in further view of Sumiya; and claim 93 was rejected as allegedly being obvious over Ren in view of L'Esperance '608. Claims 31, 33, 50-52, 56, 61 and 62 are cancelled herein, making the rejections with respect to these claims now moot. Claims 31, 33, 50-52, 56, 61, 62, 73, 74 and 79 are cancelled herein, making the rejection of these claims now moot. With respect to the remaining rejected claims, the rejections of these claims are respectfully traversed.

L'Esperance '608 and the variously combined references of Ren, Bille and Sumiya have been discussed herein above as they relate to the various elements as recited in these rejected claims.

As stated above, L'Esperance '608 fails to teach of the invention as claimed in the newly amended claim language of claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93. In particular, L'Esperance '608 fails to teach or suggest the provision of a laser having a **fundamental ultraviolet wavelength** within a

Fright St.

range of **193-220** nm exiting from the laser as claimed by claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93, much less that such a fundamental ultraviolet wavelength laser beam has an exit energy level of **no greater than 10 mJ per pulse**, as claimed by claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93.

The specific teachings of Ren, Bille and Sumiya are discussed above with respect to these particular limitations of claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93. In particular, Ren relates to a **non**-scanned, **infrared** laser having a **50** mJ/pulse output-**FIVE TIMES** that claimed by claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93. Bille teaches a method for examining eyes, having nothing to add with respect to the type and/or power level laser to use to ablate corneal tissue. Similarly, Sumiya teaches a general technique for scanning an ablating laser beam having non-uniform beam intensity characteristics in a scanned x-direction and uniform beam intensity characteristics in the y-direction, but adds nothing with respect to the noted energy level or <u>focusing</u> deficiencies of the base reference, i.e., L'Esperance '608.

For these and other reasons, claims 28-30, 36, 40, 45, 48, 49, 53-55, 57-60, 63-68, 78, 80, 81, 85, 87-89 and 93 are patentable over the prior art of record. It is therefore respectfully requested that the rejections be withdrawn.

Claims 100-104

Claims 100-104 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Parel in view of Ren, but the cancellation of claims 100-104 made herein renders this rejection now moot.

Bille

Claim 105 was rejected under 35 U.S.C. § 103 as allegedly being obvious over Ren in view of Bille. The rejection is respectfully traversed.

Claim 105 is dependent from claim 90, and is patentable for all the reasons that claim 90 is patentable.

Claim 105 recites selection of a laser having a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from the laser at an energy level of less than 10 mJ per pulse.

As discussed above, Ren teaches the use of a <u>non-scanned</u>, near-infrared laser having a fundamental output wavelength of **1064** nm and energy level of the fundamental output wavelength laser beam of **50** mJ/pulse—**FIVE TIMES** that recited by claim 105.

Bille relates to eye examination, and has nothing to do with an <u>ablating</u> laser beam for corneal <u>reshaping</u>, the <u>type</u> laser to be used for ablating corneal tissue, or the energy level of the <u>fundamental</u> output laser beam, as claimed by claim 105. Therefore, it is respectfully submitted that the combination of Bille with Ren is improper as it relates to claim 105.

Moreover, even if Bille is combined with Ren, that combination would nevertheless still fail to teach or suggest the selection of a laser having a **fundamental ultraviolet wavelength** within a range of **193-220 nm** exiting from the laser at an energy level of **less than 10 mJ per pulse**, as claimed by claim 105.

Accordingly, it is respectfully submitted that claim 105 is patentable over the prior art of record.

Conclusion

The present invention affords LOW POWER, scanning, OVERLAPPING corneal RESHAPING in a way which assures uniform corneal ablation. (See, e.g., the originally filed spec., page 16, lines 11 to 32).

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect of this Reissue is earnestly solicited.

Respectfully submitted,

William H. Bollman Reg. No. 36,457

Farkas & Manelli PLLC 2000 M Street, N.W. Suite 700 Washington, D.C. 20036-3307

TEL: (202) 261-1020

FAX: (202) 887-0336